



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,970	11/03/2000	Adrian Elmer Leek	1159.2001-000	5060

21005 7590 12/29/2003

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
530 VIRGINIA ROAD  
P.O. BOX 9133  
CONCORD, MA 01742-9133

EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
----------	--------------

1645

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Appli cation No.

09/705,970

Applicant(s)

LEEK, ADRIAN ELMER

Examin er

Mark Navarro

Art Unit

1645

--The MAILING DATE of this communication appears on th e cover she et with the correspondence address --

THE REPLY FILED 25 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: \_\_\_\_\_

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

Art Unit: 1645

### ADVISORY ACTION

Applicants response filed November 25, 2003 has been received and entered.

Consequently claims 1-20 remain pending in the instant application.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. The rejection of claims 1-4, 7-11, and 14-20 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Roy is maintained.

Applicants are asserting that Roy discloses at Step 2, the exposure to 10% potassium dichromate for 1 hour at room temperature, and that this step is immediately followed by a step of washing in tap water for 5 minutes (Step 3). Applicants conclude that this step is intended to, and invariably will, remove at least the bulk of the potassium dichromate from the sample.

Applicant's further assert that in the following step, the slides are flooded with sodium metabisulfite for 2 minutes, and that this will reduce any potassium dichromate remaining on the slides. Applicants conclude that as a result of the washing, neutralization and further washing steps, the potassium dichromate is "effectively removed" from the sections and no potassium

Art Unit: 1645

dichromate oxidizer remains on the slide by the time that, the sample comes into contact with the pH 7.8 boric acid -- Borax buffer.

Applicants further assert that "As is well known pH values below 7 are acidic, while those above 7 are alkaline or basic." Applicants conclude that the hexamine solution of Roy cannot be considered "an acid source of hydrogen ions."

Applicants assertions have been fully considered but are not found to be fully persuasive.

First, Applicants assert that Roy discloses at Step 2, the exposure to 10% potassium dichromate for 1 hour at room temperature, and that this step is immediately followed by a step of washing in tap water for 5 minutes (Step 3). Applicants conclude that this step is intended to, and invariably will, remove at least the bulk of the potassium dichromate from the sample. However, Applicants are again directed back to their claims. Where is the limitation as to the amount of oxidizer that must be added? There simply isn't one. Consequently, the presence of the oxidizer even in relatively small amounts, is sufficient to anticipate the claims limitations.

Second, Applicants further assert that "As is well known pH values below 7 are acidic, while those above 7 are alkaline or basic." Applicants conclude that the hexamine solution of Roy cannot be considered "an acid source of hydrogen ions." However, Applicants are directed to a definition of pH. pH is equal to  $-\log[H^+]$ . In other words, pH is a measure of the concentration of hydrogen ions in a solution. Applicants appear to be under the impression that a pH of 7 or greater means that no hydrogen ions are present. Applicants characterization is simply incorrect.

Art Unit: 1645

While the amount of hydrogen ions present in a solution do decrease as pH rises, they are still present even at a pH of 7.8. Dorlands Medical Dictionary 27th Edition defines acid as “a proton donor.” Holmes buffer, even at a pH of 7.8 is capable of supplying protons. Granted the number of protons is reduced at pH of 7.8 compared to 1.8, however any concentration above 0 (pH = 14) is sufficient to serve as an acid source of protons.

The claims are directed to a method of staining a biological specimen with a histological stain, wherein the specimen is treated by a process that includes treatment with a corrosive reagent, the process comprising the steps of: dispensing onto a biological specimen an oxidizer that is a precursor of the corrosive reagent; and dispensing onto the biological specimen an acid source of hydrogen ions that is other than the corrosive reagent, whereby the oxidizer combines with hydrogen ions and the combination of oxidizer and hydrogen ions contacts the biological specimen, thereby treating the biological specimen with the corrosive reagent.

Roy (Stain Technology Vol. 58, No. 4, pp 215-218, 1983) discloses the visualization of *Legionella pneumophila* in paraffin sections using hexamine silver. Roy further discloses of pretreating the biological sample with potassium dichromate (oxidizer that is a precursor of the corrosive reagent), followed by treatment with Holmes boric acid-borax buffer (acid source of hydrogen ions that is other than the corrosive reagent).

Art Unit: 1645

In view that Roy disclose of staining a biological sample with a histological stain comprising dispensing an oxidizer that is a precursor of a corrosive reagent and subsequently dispensing onto the biological specimen an acid source, the disclosure of Roy is deemed to anticipate the claimed invention.

For reasons of record in the Office Action mailed August 25, 2003, as well as the reasons set forth above, this rejection is maintained.

Claims 5-6 and 12-13 are objected to as depending upon a rejected base claim, however claims 5-6 and 12-13 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Art Unit: 1645

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

  
Mark Navarro

Primary Examiner

December 23, 2003